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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information from Non-Federal Stakeholders on Progress and Accomplishments

(2010-2015) Towards the Goals of the National Vaccine Plan.

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the

Assistant Secretary for Health, National Vaccine Program Office.

ACTION: Notice.

SUMMARY:

The development of a National Vaccine Plan was mandated by Congress as a mechanism for the

Director of the National Vaccine Program (the Assistant Secretary for Health) to communicate

priorities for achieving the Program's responsibilities of ensuring adequate supply of and access

to vaccines and ensuring the effective and optimal use of vaccines. The National Vaccine Plan,

released in 2010, provides a comprehensive 10-year national strategy for enhancing all aspects of

the National Vaccine Program including: research and development, supply, financing,

distribution, safety, informed decision making by consumers and health care providers, vaccine

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preventable disease surveillance, vaccine effectiveness and use monitoring, and global cooperation (http://www.hhs.gov/nvpo/vacc_plan/index.html).

In accordance with the 2010 National Vaccine Plan (NVP), the National Vaccine Program Office (NVPO) is conducting a mid-course review of the Plan following five years of its implementation. This review is intended to ensure that the priorities and activities outlined in the NVP are appropriately aligned towards the goals described therein given significant changes in the immunization landscape that have occurred since the NVP was released in 2010.

The NVP is intended to be a national plan that includes contributions from both federal and non-federal stakeholders. In order to collect information from non-federal stakeholders in a uniform and systematic way, the NVPO is issuing a Request for Information (RFI) through a structured survey accessed on the NVPO website at http://www.hhs.gov/nvpo/vacc_plan/index.html#mid-course-review. The RFI will solicit specific information regarding the priorities, goals, and objectives within the NVP, significant accomplishments since 2010, remaining gaps, and stakeholder perspectives on priorities of the vaccine and immunization community for the remaining years of the NVP (2016-2020). Finally, stakeholders will also be provided the opportunity to briefly inform NVPO of the top contributions from their organization.

DATES: Survey responses on the National Vaccine Plan must be completed and submitted online by midnight, 12:00 a.m. EDT on [INSERT DATE 30 DAYS FOLLOWING DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

All those interested in participating in the survey to provide information on the National Vaccine Plan should do so by clicking on the survey link provided on the NVPO website at http://www.hhs.gov/nvpo/vacc_plan/index.html#mid-course-review.

FOR FURTHER INFORMATION CONTACT:

National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 690-5566; email: nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The National Vaccine Program was established in compliance with Title XXI of the Public Health Service Act (P.L. 99-660) (§2101) (42 U.S. Code 300aa-et seq (PDF - 78 KB)) to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. Development of a National Vaccine Plan has been mandated to the National Vaccine Program Office as a mechanism for the Director of the National Vaccine Program (the Assistant Secretary for Health) to communicate priorities for both federal and non-federal stakeholders regarding vaccine research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines in order to carry out the Program's responsibilities.

The immunization landscape has changed notably since the introduction of the NVP in 2010 and its subsequent implementation plan. New vaccines were developed. New vaccination related

technologies were advanced and the passage of the Patient Protection and Affordable Care Act presented a unique opportunity for vaccination with its emphasis on preventive health.

Increased access to immunizations has also changed the dynamic of immunization delivery. While increased demand for immunizations moves us toward the goal of better vaccine coverage and the reduction of vaccine preventable diseases, the costs of administering vaccines have risen over time and created additional stresses on the immunization infrastructure. These include costs for vaccine procurement, costs associated with proper vaccine storage and handling, insurance against loss, opportunity costs, and personnel costs such as managing inventory, vaccine counseling, administration, and entering data into medical records and immunization registries. Moreover, public health departments and local jurisdictions must navigate additional demands such as improving health information technology use, adherence to Meaningful Use requirements, outbreak detection and response, and public health preparedness and response efforts with limited (and oftentimes diminishing) resources. The use of social media and online communications to distribute vaccine information and misinformation has also expanded greatly in the past few years- bringing public trust in vaccines and the immunization system to the forefront of national conversations. Outbreaks of vaccine-preventable diseases such as measles and pertussis have highlighted the need for accessible and ongoing educational materials about the risks of vaccine preventable diseases and the risks and benefits of vaccinations.

Finally, the momentum built from the 2010-2020 Decade of Vaccines Initiative, emerging global health crises such as the Ebola outbreaks in Western Africa, and imported cases of vaccine-preventable diseases such as measles have highlighted that U.S. efforts to support our national

vaccine goals must also serve as building blocks for strengthening efforts towards the detection and prevention of infectious diseases world-wide.

In accordance with the 2010 National Vaccine Plan (NVP), the National Vaccine Program Office (NVPO) is conducting a mid-course review of the NVP to ensure that the goals and objectives are appropriately aligned towards the goals described therein given significant changes in the immunization landscape that have occurred since the NVP was released in 2010. This analysis could include, but may not be limited to, evaluating the priority areas described in the Plan, identifying significant accomplishments and continued areas of opportunity towards the goals and objectives outlined in the 2010 NVP, and developing updated 2015-2020 priorities and indicators to optimize implementation efforts to better align with the current immunization landscape. This input will be used to inform Departmental priorities and activities going forward.

II. Request for Information

In order to capture non-federal stakeholder input in a targeted and systematic way, NVPO is conducting a Request for Information using an on-line survey tool to compile information regarding the priorities, goals, and objectives within the NVP, significant accomplishments since 2010, remaining gaps, and stakeholder perspectives on priorities of the vaccine and immunization community for the remaining years of the NVP (2016-2020). Finally, stakeholders will also be provided the opportunity to briefly inform NVPO of the top contributions from their organization. A link to the survey and instructions for completing the survey can be accessed via the NVPO website at

http://www.hhs.gov/nvpo/vacc_plan/index.html#mid-course-review. All information collected will be aggregated and analyzed to help inform a high level summary of the overall progress towards the goals in the NVP.

All responses to this Request for Information must be submitted by completing the online survey tool. Information collection sponsored by the NVPO required for the purposes of informing the National Vaccine Program and the National Vaccine Plan is not subject to Chapter 35 of title 44, United States Code [the Paperwork Reduction Act] as indicated in 42 U.S.C. 300aa-1 note (section 321 of Public Law 99-660).

All survey submissions will become part of the public record and subject to public disclosure. While the survey tool does not solicit identifying information, submissions that contain this information will not be edited to remove any identifying.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in vaccines and immunization efforts and goals outlined in the 2010 National Vaccine Plan.

Examples of potential responders include, but are not limited to, the following:

- general public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;

- public health officials and immunization program managers;

- physician and non-physician providers that administer immunization services, including

pharmacists and community vaccinators

- representatives from the private sector.

Dated: September 25, 2015

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National Vaccine Program Office.

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